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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/812,616 03/06/97 BOEHRINGER

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EXAMINER

CHIN, C

ART UNIT	PAPER NUMBER
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1641

16

DATE MAILED: 09/01/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

<b>Office Action Summary</b>	Application No. <b>08/812,616</b>	Applicant(s) <b>Boehringer et al</b>
	Examiner <b>Chris Chin</b>	Group Art Unit <b>1641</b>

Responsive to communication(s) filed on \_\_\_\_\_.

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

Claim(s) 1, 4-23, 53, 56-63, 65-81, and 120-125 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) 15, 23, 69, and 79 is/are allowed.

Claim(s) 1, 4-14, 16-22, 53, 56-63, 65-68, 70-78, 80, 81, and 120-125 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1641

## **DETAILED ACTION**

1. The office action dated 2/23/00 is vacated in favor of the following office action. The preliminary amendment that was originally filed on January 3, 2000 (a copy of which was received via FAX on March 3, 2000) has been entered.

### *Continued Prosecution Application*

2. The request filed on 1/21/99 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/812,616 is acceptable and a CPA has been established. An action on the CPA follows.

### *Election/Restriction*

3. Applicant's election with traverse of Group I in Paper No.6 is acknowledged. The traversal is on the ground(s) that some of the groups are classified in the same class and subclass and thus would not create an undue burden on the examiner. This is not found persuasive because even though some of the groups are placed in the same class and subclass, the search for each of the groups require a different search strategy on commercial data bases since they recite some limitations that do not overlap. However, upon further consideration, claims 16-23, 53-81 and 120 will be examined along with claims 1-15 of Group I.

The requirement is still deemed proper and is therefore made FINAL.

Art Unit: 1641

Claims 1, 4-23, 53, 56-63, 65-81, and 120-125 will be examined.

***Drawings***

4. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

***Claim Rejections - 35 U.S.C. § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1, 4-6, 8, 11, 13, 14, 16-19, 21, 22, 53-58, 60, 63, 65-68, 70, 72-75, 77, 78, 80 and 120-122 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lou et al in view of Maggio et al.

Lou et al (Clin. Chem. 39/4, 619-624, 1993) disclose a method and chromatographic test strip for detection and quantitation of lipoprotein a (Lp(a)). As shown in Figure 1, the test strip comprises a sample loading area, conjugate pad, measurement region, and an end of assay indicator. The conjugate pad contains diffusible Lp(a) coated colloidal selenium particles. The measurement region contains immobilized monoclonal antibodies specific for Lp(a). The

Art Unit: 1641

antibodies are positioned in the measurement region in a ladder-bar format. An end of assay indicator is located at the end of the test strip. In use, the number of ladder bars shown in the measurement region provides an indication of the amount of Lp(a) present - see pages 619-621.

Lou et al differ from the instant invention in failing to teach configuring the disclosed test strip for sandwich immunoassays.

Maggio et al teach the advantages and disadvantages of competitive and sandwich immunoassays. Sandwich immunoassays obviate the need for antigen reagents which are required for competitive immunoassays (page 61). The antigen reagent in competitive immunoassays must be as pure as possible. Unlike in sandwich immunoassays where the labeled reagent is a labeled antibody which does not have to be highly purified (pages 184-185).

It would have been obvious to one of ordinary skill in the art to configure the test strip of Lou et al for sandwich immunoassays as taught by Maggio et al because Maggio et al teach that sandwich immunoassays provide the advantage of obviating the need for an antigen reagent, such as the Lp(a) required for the Lp(a) coated selenium particles in the conjugate pad of Lou et al. By configuring the test strip of Lou et al for a sandwich immunoassay, there would be no need for purification procedures to obtain highly purified Lp(a).

With respect to claim 120, it would have been obvious to one of ordinary skill in the art to place the test strip of Lou et al (or Lou et al as modified by the teachings of Maggio et al) in a test kit arrangement because test kits are well known in the art for their recognized advantages of convenience and economy.

Art Unit: 1641

7. Claims 7, 20, 59, and 76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lou et al in view of Maggio et al as applied to claims 1, 4-6, 8, 11, 13, 14, 16-19, 21, 22, 53-58, 60, 63, 65-68, 70, 72-75, 77, 78, 80 and 120-122 above, and further in view of Weng et al.

See above for the teachings of Lou et al and Maggio et al.

Lou et al and Maggio et al further differ from the instant invention in failing to teach the use of particles to indirectly immobilize the antibodies in the capture zone(s) of the test strip.

Weng et al (U.S. Patent 4,740,468) teach the use of particles to indirectly immobilize antibodies to a specific reagent zone of a chromatographic test strip (col. 13, line 50, to col. 14, line 68).

It would have been obvious to one of ordinary skill in the art to use particles, as taught by Weng et al, to immobilize the antibodies in the capture zone of the test strip of Lou et al, as modified by the teachings of Maggio, because Weng et al show it to be conventional in the art to immobilize antibodies to a chromatographic test strip via the use of particles. Moreover, particles provide the advantage of increased surface area so that more antibodies can be immobilized to the capture zone.

8. Claims 71 and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lou et al in view of Maggio et al as applied to claims 1, 4-6, 8, 11, 13, 14, 16-19, 21, 22, 53-58, 60, 63, 65-68, 70, 72-75, 77, 78, 80 and 120-122 above, and further in view of Kang et al.

Art Unit: 1641

See above for the teachings of Lou et al and Maggio et al.

Lou et al and Maggio et al further differ from the instant invention in failing to teach a multi-test strip embodiment wherein all of the test strips contact a common sample receiving zone.

Kang et al (U.S. Patent 5,559,041) disclose a multizone chromatographic test strip for performing sandwich or competitive immunoassays. Figure 5 shows an embodiment wherein multiple test strips are configured around a common sample receiving zone (310) for the purpose of assaying for one or more analytes in a given sample (col. 4, line 67, to col. 5, line 21).

It would have been obvious to one of ordinary skill in the art to configure the test strips of Lou et al around a common sample receiving zone as taught by Kang et al because Kang et al teaches that such a configuration provides the advantage of being able to perform multiple assays on the same sample for one or more desired analytes.

9. Claims 9 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lou et al in view of Maggio et al as applied to claims 1, 4-6, 8, 11, 13, 14, 16-19, 21, 22, 53-58, 60, 63, 65-68, 70, 72-75, 77, 78, 80 and 120-122 above, and further in view of Katz et al.

See above for the teachings of Lou et al and Maggio et al.

Lou et al and Maggio et al further differ from the instant invention in failing to teach the use of ligand/receptor system to immobilize the antibodies in the capture zone of the test strip.

Katz et al (U.S. Patent 4,496,654) teaches the use of an avidin/biotin system for immobilizing antibodies to a solid support. Avidin is first immobilized to a solid support.

Art Unit: 1641

Biotinylated antibodies are then applied to the avidin coated solid support. The biotin portion of the biotinylated antibodies binds to the avidin to immobilize the antibodies to the solid support.

It would have been obvious to one of ordinary skill in the art to use the avidin/biotin system of Katz et al to immobilize the antibodies in the capture zone of the test strip of Lou et al, as modified by the teachings of Maggio et al, because the highly specific affinity avidin for biotin provides for improved immobilization of antibodies to the test strip.

10. Claims 12, 64, and 123 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lou et al in view of Maggio et al as applied to claims 1, 4-6, 8, 11, 13, 14, 16-19, 21, 22, 53-58, 60, 63, 65-68, 70, 72-75, 77, 78, 80 and 120-122 above, and further in view of Bunting.

See above for the teachings of Lou et al and Maggio et al.

Lou et and Maggio et al further differ from the instant invention in failing to teach the use of a receptor/hapten system for immobilizing the antibodies in the capture zone of the test strip.

Bunting (U.S. Patent 4,271,140) teach the use of a receptor/hapten system for immobilizing antibodies to a solid support (cols. 3-6).

It would have been obvious to one of ordinary skill in the art to use the receptor/hapten system of Bunting to immobilize the antibodies in the capture zone of Lou et al's test strip, as modified by the teachings of Maggio et al, because the receptor/hapten system of Bunting provides the advantage of being able to recover bound analyte from the capture zone (col. 3, lines 36-46).

Art Unit: 1641

11. Claims 10 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lou et al in view of Maggio et al as applied to claims 1, 4-6, 8, 11, 13, 14, 16-19, 21, 22, 53-58, 60, 63, 65-68, 70, 72-75, 77, 78, 80 and 120-122 above and further in view of Eisinger et al.

See above for the teachings of Lou et al in view of Maggio et al.

The combination of Lou et al in view of Maggio et al differs from the instant invention in failing to teach the use of binding reagent in the detection that can bind to a complex of analyte and a binding reagent.

Eisinger et al (U.S. Patent 4,943,522) discloses a chromatographic immunoassay device. The device includes a detection zone which contains an immobilized specific binding reagent that binds to complexes of analyte and another specific binding reagent (col. 7, lines 61-66).

It would have been obvious to one of ordinary skill in the art to use a binding reagent that is specific for complexes of analyte and another specific binding reagent, as taught by Eisinger et al, in the device of Lou et al, as modified by Maggio et al, because Eisinger et al shows it to be well known and conventional in the art to use such binding reagents in the detection zone of chromatographic immunoassay devices, such as the device of Lou et al.

***Claim Rejections - 35 U.S.C. § 102***

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 1641

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 124 and 125 are rejected under 35 U.S.C. 102(b) as being anticipated by Lou et al.

See above for the teachings of Lou et al. Lou et al discloses a chromatographic immunoassay device for performing competitive immunoassays.

***Allowable Subject Matter***

14. Claims 15, 23, 69 and 79 are allowed.

***Conclusion***

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chris Chin whose telephone number is (703) 308-3991. The examiner can normally be reached on Monday-Thursday from 8:30 am to 6:00 pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399. The appropriate fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Art Unit: 1641

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

cchin/cc  
August 30, 2000

*Christopher L. Chin*

CHRISTOPHER L. CHIN  
PRIMARY EXAMINER  
GROUP 1800/641